17 CFR Part 140

Change in Titles of Personnel

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule; correction.

SUMMARY: CFTC is correcting an error in a change to titles of personnel previously published in the Federal Register on May 13, 1996, (61 FR 21955). The original document contained an erroneous paragraph reference.

EFFECTIVE DATE: May 13, 1996.

FOR FURTHER INFORMATION CONTACT: Stacy Dean Yochum, Counsel to the Executive Director, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St. NW., Washington, DC 20581, (202) 418–5157.

Correction

In the final rule FR Doc. 96–11923, beginning on page 21954 in the Federal Register issue of May 13, 1996, make the following correction:

On page 21955, in the first column, in amendment 4. to § 140.735–8, the reference to ''paragraph (a)(3)'' is corrected to read ''paragraph (b)(3).''

Dated: March 14, 1997.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 97–6971 Filed 3–19–97; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two new animal drug applications (NADA's) from Biocraft Laboratories, Inc., to Teva Pharmaceuticals USA.

EFFECTIVE DATE: March 20, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407, has informed FDA that it has transferred ownership of, and all rights and interests in, NADA's 65–492 (amoxicillin trihydrate tablets) and 65–495 (amoxicillin trihydrate for oral suspension) to Teva Pharmaceuticals USA, 650 Cathill Rd., Sellersville, PA 18960. Accordingly, the agency is amending the regulations in 21 CFR 520.88b and 520.88f to reflect the transfer of ownership.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.88b [Amended]

2. Section 520.88b *Amoxicillin trihydrate for oral suspension* is amended in paragraph (c) by removing the number ''000332'' and adding in its place ''000093''.

§ 520.88f [Amended]

3. Section 520.88f *Amoxicillin trihydrate tablets* is amended in paragraph (b) by removing the number ''000332'' and adding in its place ''000093''.

Dated: March 11, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–7002 Filed 3–19–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 803 and 804

[Docket No. 91N–0295]

RIN 0910–AA09

Medical Devices; Medical Device Reporting; Annual Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its medical device manufacturer and distributor adverse event certification regulations. The revised certification requirements allow manufacturers and distributors to designate more than one certifying official, who would each sign a certification statement for his or her identified organizational component or site; amend the certification statement to minimize concerns relating to liability from unintentional reporting errors; and indicate that the certifying official is making the certification statements, to the best of his/her knowledge and belief. This action is being taken to help FDA carry out its public health protection responsibilities relating to medical devices. This action provides reporting entities with greater flexibility in the certification process while reducing the regulatory burden.

DATES: Effective May 19, 1997. Submit written comments on the information collection requirements by April 21, 1997.

ADDRESSES: Submit written comments on the final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Earl W. Robinson, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2735.

SUPPLEMENTARY INFORMATION:

I. Background

Section 519(d) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(d)) provides that each manufacturer, importer, and distributor shall certify that they did file a certain number of medical device reports (MDR's) in the previous 12 months or they did not file any MDR's. Distribution certification regulations implementing this statutory provision became effective on May 28, 1992, when requirements relating to distributor reporting that were proposed in the Federal Register of November 26, 1991 (56 FR 60024), became final by operation of law. In the Federal Register of December 11, 1995 (60 FR 63578), FDA published a final rule similar to the distributor certification provisions, that required manufacturers to submit certification statements (§ 803.57 (21 CFR 803.57)) (hereinafter referred to as the December 1995 final rule). Distributors and manufacturers were required to certify that they filed reports for all reportable events required under